

PRM161**ASSESSING THE METHODOLOGICAL VALUE OF DIGITAL REAL-TIME COLLECTION OF QUALITATIVE CONTENT IN SUPPORTING IN-DEPTH QUALITATIVE INTERVIEWS EXPLORING THE SYMPTOMS AND IMPACTS OF GOUT ON HEALTH-RELATED QUALITY OF LIFE**Rudell K¹, Tatlock S², Panter C², Arbuckle R², Symonds T¹¹Pfizer Ltd, Tadworth, UK, ²Adelphi Values Ltd, Bollington, UK

OBJECTIVES: Gout is the most common arthritic condition, but research of Gout patient experiences is limited. Qualitative interviews are a valid and well-accepted means of gaining in-depth insight into the patient experience, but are typically conducted in artificial environments relying on patient recall. Novel digital methods of collecting qualitative data through real-time data capture (RTDC) have recently emerged and have stronger ecological validity. The objective of this research was to assess the added methodological value of analyzing audio/visual data recorded and submitted by gout patients through a mobile phone application while experiencing flares, in addition to traditional patient interviews. **METHODS:** Concept elicitation interviews were conducted with 20 American gout patients using open-ended exploratory questions to facilitate spontaneous elicitation of content. Following interviews, 50% of the sample took part in a RTDC exercise by submitting self-recorded videos and images in response to six tasks issued on a mobile phone application over seven days. All data were subject to thematic analysis using Atlas.ti. Interviews and RTDC data were compared in terms of conceptual coverage and insights. **RESULTS:** Qualitative analysis demonstrated both forms of data collection led to the identification of the same symptoms and impacts with no additional concepts identified in either form of data. Symptoms and impacts of the disease during flares were high. RTDC data provided additional insight into the severity of symptoms and level of impact burden, specifically with regards to images of the level of swelling experienced during a flare and sleep disturbances through videos recorded by patients at the time of disturbance. **CONCLUSIONS:** Whilst traditional patient interviews remain the gold standard in exploring the symptoms and impacts of a condition, RTDC was found to provide additional valuable insights in this sample of gout patients, which can inform future measurement strategies and enhance the field of patient-centered research.

PRM162**WHAT IS THE APPROPRIATE COMPARATOR HEALTH STATE TO USE IN TIME TRADE-OFF STUDIES?**

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OBJECTIVES: Studies to produce utility values for the EQ-5D-5L instrument are ongoing internationally. These include the valuation of 10 EQ-5D-5L health states using the time trade-off (TTO) method. In some of the studies carried out to date, relatively low mean TTO values for mild health states have been observed. It is hypothesised that this is because the health states under evaluation are being compared to “full health”, whereas in previous studies they were compared to 11111 (the “best” health state in the descriptive system). The objective is to assess differences in TTO valuations using two different comparators (full health and 11111). **METHODS:** Preferences for EQ-5D-5L health states were elicited from a broadly representative sample of the UK general public. TTO data were collected using computer-assisted personal interviews, carried out in respondents’ homes. Respondents were randomly allocated to one of two arms: in arm 1 the comparator health state was full health; in arm 2 the comparator health state was 11111. After completing 10 TTO valuations, respondents were asked follow-up questions which sought to examine their interpretations of the term “full health”. **RESULTS:** 450 interviews were completed in mid-2014. Health state 11111 was almost always given a value of 1; yet the majority of respondents who self-reported as being in 11111 did not consider themselves to be in “best imaginable health”. Preliminary analyses suggest that the use of 11111 (rather than full health) as the comparator does not increase the average values elicited for mild health states. A sizeable minority of respondents did not agree that 11111 and full health are equivalent. Vision and spirituality were mentioned by respondents as examples of important aspects of health not covered by 11111. **CONCLUSIONS:** The low observed values for mild EQ-5D-5L health states cannot be explained by the choice of comparator health state alone.

PRM163**THE DEVELOPMENT AND PRELIMINARY VALIDATION OF THE MANCHESTER EARLY MORNING SYMPTOMS INDEX (MEMSI) FOR PEOPLE WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)**Garraw AP¹, Yorke J¹, Khan N², Tyson S¹, Singh D³, Vestbo J⁴¹University of Manchester, Manchester, UK, ²The Medicines Evaluation Unit, Manchester, UK,³University of Manchester, Medicines Evaluation Unit, Manchester, UK, ⁴The University of Manchester, Manchester, UK

OBJECTIVES: Early morning symptoms (EMS) of COPD are associated with poor health, impaired daily activities and increased exacerbation risk. We describe the development and preliminary validation of the Manchester Early Morning Symptom Index (MEMSI) to quantify EMS in COPD. **METHODS:** Potential items were identified from interviews and focus groups with COPD and non-COPD participants. Cognitive de-briefing elucidated the relevance and understanding of the potential items followed by a cross-sectional study to finalise the items for inclusion. The draft scale was completed twice, one week apart to assess test-retest reliability. The St George's Respiratory Questionnaire (SGRQ), modified MRC Dyspnoea Scale, FACIT fatigue scale and Hospital Anxiety and Depression Scale (HADS) evaluated convergent validity. Hierarchical methods and Rasch analysis informed item reduction and assessed uni-dimensionality. **RESULTS:** 36 patients with COPD initially identified 22 items. The cross sectional study included 203 COPD patients (GOLD: I: 14% II: 41% III: 25% IV: 7%, male: 63%, mean age 64.7, SD: 7.5 years) and 50 age and gender matched non-COPD controls. 12 items were removed during hierarchical methods. The MEMSI demonstrated excellent internal consistency (Cronbach's alpha 0.9) and good test-retest repeatability ($r=0.82$). The scale also showed moderate-good correlation with

the Total SGRQ score ($r=0.73$) and Symptoms ($r=0.62$); Activity ($r=0.55$), Impact ($r=0.72$) subscales; the modified MRC Dyspnoea scale ($r=0.54$), FACIT-F ($r=-0.66$); HADS Anxiety ($r=0.53$) and Depression ($r=0.54$). The MEMSI also demonstrated good overall fit to the Rasch model (Chi-squared 26.6; df 20; $p=0.26$) and distribution of item scores. **CONCLUSIONS:** The final MEMSI contains 10-item and is a reliable, valid, uni-dimensional self-reported outcome measure of early morning symptoms for people with COPD. It is quick and simple making it suitable for use in research and practice. Further work is underway to determine the minimal clinical important difference.

PRM164**AN ELECTRONIC VERSION OF THE PDQ-39: ACCEPTABILITY TO RESPONDENTS AND ASSESSMENT OF ALTERNATIVE RESPONSE FORMATS**

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OBJECTIVES: Firstly, to migrate the paper-based version of the PDQ-39 to a computer based platform and assess its usability and acceptability to respondents. Secondly, to investigate the impact of implementing non-response options on response rates and data completeness. **METHODS:** Six people with Parkinson's (PwP) participated in cognitive interviews in order to assess the usability and acceptability of the electronic version of the PDQ-39, the ePDQ. This was followed by an online survey of 129 PwP, randomly assigned to one of two groups; one required to provide a response to every item and one with the option to skip any item they did not wish to answer. **RESULTS:** Cognitive interviews indicated that the ePDQ is acceptable to PwP, with positive feedback regarding layout, features and functionality. 125 PwP fully completed the ePDQ. Following randomization 60 participants completed the forced response ePDQ and 65 completed the non-forced version. Response rates of 98.4% were achieved for the forced response ePDQ and 95.6% for the non-forced. Missing value analyses calculated levels of missing data at below 5% in the non-forced sample. **CONCLUSIONS:** The ePDQ is user-friendly and acceptable to respondents. Additionally, there appears little difference when implementing non-response options on response rates and data completeness.

PRM165**EFFICACY OF VIRTUAL REALITY EXPOSURE THERAPY IN THE MANAGEMENT OF SYMPTOMS ASSOCIATED WITH POST TRAUMATIC STRESS DISORDER**

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OBJECTIVES: Management of symptoms and illness for post traumatic stress disorder (PTSD) requires effective and prolonged psychiatric support. Re-experiencing traumatic memories and events via virtual reality exposure therapy (VRET) can lead to reduction of illness and symptoms associated with PTSD. This systematic literature review aims to demonstrate the value of VRET in the management of illness and symptoms associated with PTSD. **METHODS:** Studies published in the English language for PTSD and VRET were retrieved from Embase, PubMed, and Cochrane databases using relevant search strategies. Two researchers are independently reviewing studies as per the Cochrane methodology for systematic literature reviews. We considered VRET as a tool to deliver therapy programs via a virtual platform to patients suffering from PTSD. The main outcome will be improvement in symptoms such as anxiety, various phobias and depression developed as a result of PTSD. Outcomes will be measured as change in baseline characteristics in patients using VRET, by using questionnaires specific to the symptoms being measured such as Beck's Anxiety Inventory, Beck's Depression inventory-II (BDI-II), Clinician-Administered PTSD Scale (CAPS), and patient reported outcomes. **RESULTS:** In total, 2574 potentially relevant studies were retrieved from the databases and are being screened for inclusion in the review. The detailed results from the systematic review will be presented in the poster. **CONCLUSIONS:** The evidence from this systematic literature review will hopefully suggest the role of VRET as a promising new tool for managing PTSD from a psychotherapeutic perspective.

PRM166**QUALITY OF LIFE ELEMENTS IN SCHIZOPHRENIA FOR PATIENTS AND CARERS OFFER CHALLENGES TO AND OPPORTUNITIES FOR INTERVENTION**Floyd D¹, Gemmell E², Brown J¹¹PHMR Associates, London, UK, ²PHMR Associates, Newcastle upon Tyne, UK

OBJECTIVES: Schizophrenia is responsible for high levels of individual morbidity: acute schizophrenia had the highest disability score of any condition in the 2010 Global Burden of Disease study. Consequently, quality of life (QoL) overall and related to health is a major issue for patients, as well as their families/carers. **METHODS:** We undertook a pragmatic literature search of publications relating to QoL and schizophrenia over the past 7 years to identify main themes and trends. **RESULTS:** Patients: Patient-reported QoL is often over-estimated compared to objective QoL as measured by health care professions, particularly during psychotic episodes. Factors that appear to be adversely associated with QoL include symptoms, treatment side effects, physical mobility, lack of relationships, daily activity, housing, social stigma and self-stigma. In some cases, there is a complex cause and effect relationship. Families/carers: Those looking after patients with schizophrenia suffer impaired QoL and this can have an impact on the whole household and its social milieu. Poor carer QoL can ultimately impair levels of care and increase risk of mistreatment, which in turn risks a relapse of symptoms and ultimately hospitalisation. On the other hand, the experience of caring for a patient with schizophrenia may lead to personal emotional/psychological growth. Disease insight and education for some schizophrenia sufferers can lead to diminished QoL and an increased risk of suicide. On the other hand, disease understanding can help improve treatment adherence. **CONCLUSIONS:** QoL in schizophrenia is complicated and must be fully understood to help develop effective programmes to improve QoL for sufferers and their families/carers. Programmes that do not reflect this complexity may increase risk of symptom recurrence and even suicide. Thus, when devising interventional programmes to supplement drug treatment for management of schizophrenia, a range of patient- and carer-related factors must be considered.

PRM167

COMPARABILITY OF INTERVIEW AND SELF-ADMINISTRATION OF THE FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY-TUBERCULOSIS (FACIT-TB) INSTRUMENT IN IRAQI PULMONARY TUBERCULOSIS PATIENTS

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OBJECTIVES: To investigate the extent to which two different modes of administration (interview by a trained interviewer versus self-administration) yielded a comparable estimate of health-related quality of life (HRQL) in pulmonary tuberculosis (PTB) patients. **METHODS:** The study was conducted between September 1st 2012 and July 31st 2013, among consecutive PTB patients treated at Thoracic and Respiratory Disease Specialist Centre in Baghdad, Iraq. The mode of administration of the Functional Assessment of Chronic Illness Therapy-Tuberculosis (FACIT-TB); a new tuberculosis (TB) - specific instrument, at baseline was registered in 305 subjects. **RESULTS:** Although the FACIT-TB was designed for self-administration, most patients in our sample (N = 193, 63.278%) requested some help from the interviewer to fill out the questionnaire. Mann Whitney U test showed that those patients capable of self-administration were younger (38.16 ± 12.93 versus 43.58 ± 16.41 years, P = 0.005) and required less time to complete the questionnaire compared to those who interviewed by a trained interviewer (14.64 ± 3.24 versus 17.22 ± 2.61 minutes, P < 0.001), while Chi-Square statistics showed that this group of patients had a higher education level (P < 0.001). No differences in gender were observed. HRQL score across all domains for those who interviewed by a trained investigator was slightly lower than those who answered the questionnaire by self-administration. However, the results did not reach statistical significance (P > 0.05). **CONCLUSIONS:** Technical equivalence has been demonstrated in the sample of PTB patients in Iraq. FACIT-TB instrument is flexible and it is able to accommodate the needs of patients with diverse social, educational, and functional skills. Technical equivalence across different modes of administration of questionnaire permits unbiased assessment of the impact of the disease and its treatments on patients' HRQL.

PRM168

HEALTH RELATED QUALITY OF LIFE IN CANCER PATIENTS: EVALUATION WITH A SELF-ADMINISTERED IPAD APPLICATION

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OBJECTIVES: Cancer has the second highest mortality rates after cardiovascular diseases in the world. Advances in treatment options caused significant enhancements in survival of cancer patients. However, the major parameter affecting treatment success and treatment adherence in these patients is the quality of life (QoL). We aimed to develop a self-administered iPad application for evaluation of QoL in a short questionnaire. **METHODS:** As part of routine practice in Preventive Oncology Department EORTC QLQ-C30 was administered to 1549 cancer patients treated in Hacettepe University Oncology Hospital. We determined 10 questions that explains most of the variation in QoL using factor analysis, and designed a new application for iPad, where patients can record responses themselves. **RESULTS:** The 10 factors that described by the factor analysis had the power of 74.2% explaining QoL variances. The reliability analysis of these factors showed a Cronbach alpha coefficient of 0.75. The new self-administered iPad application was tested in a pilot study that conducted in 127 patients taking chemotherapy regimens in the outpatient setting. The validity and reliability analyses revealed that the new application can be effectively used in Turkish cancer patients. **CONCLUSIONS:** Our results revealed that our software application will be useful and efficient for monitoring of the changes in QoL during their treatment course. Furthermore, this kind of mobile applications may be practical for health professionals in daily routine clinical assessments of patients. Also, the audio and visual enhancements in electronic applications provide increased accessibility for the cancer patients.

PRM169

THE SELECTION OF APPROPRIATE HEALTH STATE UTILITY VALUES (HSUVS) FOR HEALTH TECHNOLOGY ASSESSMENT (HTA): LESSONS TO BE LEARNT

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OBJECTIVES: Incorporation of health-related quality of life (HRQoL) evidence into economic models is a requirement of many countries for the purposes of Health Technology Assessment (HTA), and therefore appropriate health state utility values (HSUVs) are often sought. The objective of this review was to: (i) identify and summarise the principal limitations of HSUVs used in recent submissions appraised by the National Institute for Health and Care Excellence (NICE) and (ii) produce a categorical checklist that can be used by manufacturers to reduce uncertainty when selecting HSUVs for HTA. **METHODS:** Evidence appraisal documents for the 50 most recently published technologies assessed by NICE were retrieved in June 2014. Economic models were assessed and utility inputs reviewed. Critiques of the utilities reported by the evidence review group or final appraisal committee were extracted, reviewed and categorised. **RESULTS:** Of the appraisals reviewed (43 single technology appraisals (TAs) and 7 multiple TAs), utility inputs were either sourced from the literature (n=27), published mapping algorithms (n=11), de novo mapping algorithms (n=2), or derived from clinical trials (n=10). The concerns expressed by review groups can be categorised into four categories: (i) generalisability – relevance of HSUVs to UK clinical practice, deviation from NICE scope, and the use of other countries' valuations for health states; (ii) HSUV selection – inadequate justification of HSUVs, and lack of consideration for covariates and disutilities; (iii) mapping algorithms – use of non-validated or non-peer-reviewed publications, incomplete reporting of key model information, and ambiguity regarding selection and justification of mapping function; (iv) risk of bias – sample size, instrument response rates, and general study quality identified as factors affecting HSUV validity. **CONCLUSIONS:** The selection of appropriate HSUVs is critical to reduce uncertainty in economic

models. A checklist based on critiques of recent HTAs will be a useful tool for manufacturers when selecting relevant HRQoL parameters.

PRM170

TRANSLATION AND LINGUISTIC VALIDATION OF THE ELECTRONIC COLOMBIA SUICIDE SEVERITY RATING SCALE IN ASIA-PAC

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OBJECTIVES: The Columbia Suicide Severity Rating Scale (C-SSRS) has been developed into an electronic self-rated version (the e-CSSRS) in order to facilitate compliance with regulatory requirements for prospective monitoring of suicidal ideation and behaviours. The e-CSSRS v2.0 for IVRS has been translated and linguistically validated for use in over 60 countries. Whilst translating and linguistically validating the scale it was noted that particularly in the Asia-Pacific region there were some challenging issues around the concept of suicide from a linguistic and cultural perspective. This study aimed to determine what these issues were and highlight how they were resolved. **METHODS:** Eighteen reports were reviewed from the Asia-Pacific region. The languages were: China-Mandarin, India-English, India-Gujarati, India-Hindi, India-Kannada, India-Malayalam, India-Marathi, India-Tamil, India-Telugu, Korea-Korean, Malaysia-English, Malaysia-Malay, Malaysia-Mandarin, Philippines-English, Philippines-Tagalog, Singapore-English, Singapore-Malay, and Singapore-Mandarin. Each report was reviewed for challenges relating to translation and cultural adaptation. **RESULTS:** Across all reports specific homonymic confusions were encountered within two target languages: in Indian Hindi the same word is used for "pill" and "bullet"; in Singapore Malay the words for "end" and "saving" sound similar, occasioning confusion in prompts about attempts to end life. Translations were adapted to avoid these confusions. In two cases the use of a gun in suicide attempts was found to be rare or unknown: in Singapore English the relevant prompt was clarified to minimise confusion; for Malayalam for Kerala, where shooting is rare and hanging is common, "getting a gun" was changed to "getting a rope" wherever it appeared and for similar reasons "collecting pills" was changed to "collecting a poison." **CONCLUSIONS:** The e-CSSRS v2.0 IVRS is now available in for use in over 60 countries. Some issues were identified relating to translation and the methods of suicide in a small number of languages but these were resolved throughout the linguistic validation process.

PRM171

FROM CLINICALLY RELEVANT OUTCOME MEASURES TO QUALITY OF LIFE IN EPILEPSY

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OBJECTIVES: Utilities can be easily derived using generic quality of life (QoL) instruments. However, problems in collecting utility scores may occur because clinical evaluations still favor disease specific instruments over generic quality of life instruments for reasons of sensitivity and reliability. Especially in case of the fluctuating nature of seizures in epilepsy, generic QoL-instruments are often found to be unsuitable for outcome research. A proposed method to bridge the gap between clinically relevant outcome measures and QoL is to derive utility scores for epilepsy health states. The aim of this study is to develop a scoring algorithm to transform epilepsy health states into utility scores. **METHODS:** The proposed scoring algorithm was based on valuations of health states generated by the Time Trade-Off (TTO) method. The TTO was based on clinically important attributes (seizure frequency, seizure severity and treatment related side-effects). A full factorial design was used which resulted in 78 scenarios. Besides standard demographics, every participant was asked to value 10 or 11 different health states. A multilevel regression analysis was performed to account for the nested structure of the data. The TTO was conducted using online survey software. **RESULTS:** In total 531 subjects of the general population, with an average age of 42 years, have participated in the TTO study. Preliminary results show that the best health state (no seizures and no side-effects) is estimated at 0.89 utility and the worst state (seizures twice a day, many side-effects, type 5 seizure) is estimated at 0.16. **CONCLUSIONS:** This study provides a scoring algorithm for transforming clinically relevant outcome measures of epilepsy into utility estimates which can be incorporated into economic evaluations. Although seizure frequency is the most commonly reported primary outcome measure in epilepsy research, this study suggest that the impact of seizure severity alone should not be underestimated.

PRM172

AN ANALYSIS OF THE HEALTH TECHNOLOGY ASSESSMENT RECOMMENDATION AND GUIDANCE ON USE OF EQ-5D-5L IN COST-EFFECTIVENESS MODELING

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OBJECTIVES: Several national health technology assessment (HTA) bodies including the National Institute for Health and Care Excellence (NICE) for England and Wales recommend EQ-5D as the preferred health-related quality of life (HRQL) measure for use in cost-effectiveness analyses. This study aims to evaluate the recommendation and impact of using EQ-5D-5L versus EQ-5D-3L for cost-effectiveness modeling in HTA submission guidelines and subsequent reimbursement decisions. **METHODS:** A targeted review of national HTA submission modeling guidelines since the introduction of the EQ-5D-5L measure was carried out for the UK and France. The cost-effectiveness modeling guidelines were assessed for the requirements for EQ-5D at either level. The impact of guideline requirements on submissions were analysed by examining the presence of EQ-5D-5L in the 20 most recent technical appraisal manufacturer submissions for each HTA body. **RESULTS:** While all HTA bodies recommended the use of EQ-5D as a generic measure of HRQL, only NICE specifically recommended EQ-5D-5L. However, it was not a requirement. Of the latest published guidance only NICE and the Scottish Medicines Consortium had one EQ-5D-5L submission each. Despite evidence suggesting increased sensitivity and reduced ceiling